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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,377	01/23/2004	Yat Sun Or	ENP-074 (4014.1074 US)	7571

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,377	OR, YAT SUN	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 9/27/2006 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 13-14 have been canceled.

2. Remarks drawn to rejections under double patenting, 35 USC 112, first and second paragraphs, 102(b) and 103(a).

Claims 1-12 and 15 are pending in the case.

Double Patenting

The terminal disclaimers filed on 3/30/2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,878,691; 6,674,998; 6,645,941 and Application Nos. 10/946,339; 10/840,949; 10/758,409; 10/436,622 and 11/008,581 have been reviewed and are accepted. The terminal disclaimers have been recorded. The obviousness-type double patenting rejections of the instant claims over U.S. Patent Nos. 6,274,715; 6,355,620; 6,054,435; 6,075,133; 6,046,171; 5,922,683 have been overcome by amendments.

Therefore, the obviousness-type double patenting rejection of record is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1 and 15 under 35 U.S.C. 112, first paragraph, for lack of enablement (scope) advanced in the previous office action is being maintained for reasons of record.

Applicants have argued that:

1. The instant specification has examples showing enablement for the macrolide rings containing at least two nucleophilic moieties and that such a process can be extended to other systems.

2. The macrocyclic structure shown by the Examiner has the lone pair on oxygen delocalized and such a system will not undergo the bridging as instantly claimed and nucleophilicity is not defined by the availability of unpaired electron.

3. The claims embrace only processes that achieve a bridged macrocyclic product and do not embrace any inoperative embodiments and therefore are enabled.

This is not found to be persuasive.

The instant process is drawn to the use of a macrocyclic compound characterized by the presence of at least two nucleophilic moieties. Atoms or groups that bear an electron pair are also nucleophiles. Hence the structure shown by the Examiner in the previous rejection falls under the category of a macrocyclic compound having at least two nucleophilic moieties. Such a macrocycle cannot form a bridge as instantly claimed. Hence any macrocycle will not form a bridge. The instant specification is enabling only for macrolides like erythromycin.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 3-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome in view of applicants arguments. The rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Or et al (WO 99/21864) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the prior art does not teach or suggest the use of a single bridging component characterized by at least two leaving groups to form the bridge. This is not found to be persuasive. Instant claim 15 is drawn to the use of a bridging component characterized by at least two nucleophilic leaving groups. This recitation is seen to include single or multiple bridging components. The prior art teaches bridging of a macrocyclic compound using a bridging component that has at least two nucleophilic leaving groups and hence meets the limitations of the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Or et al (WO 99/21864) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the fact that the present process required fewer steps proved that the process is novel and the instant process is not taught or suggested by Or. The instant process according to the applicants results in a bridged macrocyclic product that is different from the compound of Or.

This is not found to be persuasive.

Or et al teaches a process for making a bridged macrocyclic compound (formula 14, page 36) comprising the reaction of the macrocyclic compound of formula 1 (page 34, has at least two nucleophilic groups) with the bridging components $H_2N\text{-}(CH_2)_m\text{-A-B-D-X}$ and $(CH_2)_2\text{-C=}CH_2$ (the second bridging component with the double bond forms a pi-allyl complex with a metal; page 36, scheme 3) to yield the bridged product. The macrocyclic compound of Or is a derivative of erythromycin and is an antibiotic and is structurally very close to the macrocyclic compound used for the said bridging in the instant process. The fact that bridging can be achieved in fewer steps compared to that of Or can be recognized by one of ordinary skill in the art and is also the motivation for carrying out the process as instantly claimed.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988 and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

Claims 1-12 and 15 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

12/11/06

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623